

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW YORK**

JEFFRY LEROY, as Co-Guardian of SILVIA LEROY,  
Incapacitated Person, SHIRLEY LICIN, as Co-Guardian of  
SILVIA LEROY, Incapacitated Person, and JEFFRY LEROY,  
Individually,

Plaintiff,

v.

HEATHER HUME, M.D., MINDY BRITTNER, M.D., MIRA  
JOHN, M.D., MOUNT SINAI HOSPITAL, MARY  
TOUSSAINT-MILORD, M.D., KANIZ B. BANU, M.D.,  
MAHREEN AKRAM, M.D., JAMIE CELESTIN-  
EDWARDS, CNM, BROOKDALE HOSPITAL MEDICAL  
CENTER, JILL BERKIN, M.D., and KEVIN TROY, M.D.,

Defendants.

Civil Action No.  
1:20-cv-05325

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**DEFENDANTS' STATEMENT OF SUPPLEMENTAL AUTHORITY IN OPPOSITION  
TO PLAINTIFF'S MOTION TO REMAND**

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COME NOW, Defendants HEATHER HUME, M.D., MOUNT SINAI HOSPITAL, JILL  
BERKIN, M.D., KEVIN TROY, M.D. (herein the "Mount Sinai Defendants"), by and through  
their undersigned counsel, hereby submit this Statement of Supplemental Authority in Opposition  
to Plaintiff's Motion to Remand:

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<sup>1</sup> Available at: <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf>.

## I. INTRODUCTION

In response to Defendants’ request for oral argument, on July 1, 2021 this Court ordered: “To the extent that there are issues which defendants wish to clarify, defendants are instructed to brief those issues in writing no later than July 13, 2021. Plaintiffs’ opposition, if any, shall be filed no later than July 20, 2021.” This Statement of Supplemental Authority is submitted in response to the same.

In the time since Plaintiffs filed their Reply in support of the Motion to Remand, several courts have rendered decisions regarding removal jurisdiction under the Public Readiness and Emergency Preparedness Act (the “PREP Act”), 42 U.S.C. §§ 247d-6d, 2479-6e. This Statement of Supplemental Authority addresses those decisions and explains why the approach taken by the majority of district courts should not be followed.

In brief, many, if not all, of the recent decisions granting remand share common errors in reasoning that are derived from the holdings of *Maglioli*, *Baskin*, and *Dupervil*: (1) they improperly analogize the administrative remedy of mandatory arbitration under the Railway Labor Act to the administrative remedy of no-fault benefits under the PREP Act; (2) they do not account for the fact that the PREP Act, unlike the Railway Labor Act, actually does create an “exclusive” federal cause of action; (3) they make complete preemption conditional on whether the plaintiff would be entitled to relief through the exclusive federal cause of action provided; (4) they effectively prohibit application of the complete preemption doctrine to any situation where the plaintiff has not already alleged a federal cause of action to begin with; (5) they rely on an erroneous application of the “complete preemption” doctrine to support not affording deference to Advisory Opinion 21-01’s treatment of the issue; (6) they decline to grant deference to HHS’s interpretation of the breadth of the PREP Act and its statutory framework; (7) they fail to provide any deference at all to the Secretary of HHS’s Fourth Amendment to the Declaration solely because they do not agree

with the Secretary’s reasoning under *Grable*; and (8) they perpetuate the “action versus inaction” dichotomy that HHS has expressly rejected as being contrary to the plain language of the PREP Act and its inherently broad language such as “related to.”

In contrast to the courts granting remand, one court has found that the PREP Act does trigger complete preemption: *Rachel v. Natchitoches Nursing & Reab. Ctr.*, No. 1:21-cv-334 (W.D.L.A. Apr. 30, 2021). There, the court found that the PREP Act did confer removal jurisdiction, and directed limited discovery to determine whether the claims fell under the PREP Act. *Id.*

Here, no discovery is needed to ascertain whether the claim fall under the PREP Act because the Complaint makes clear that it “relates to” the “administration” of “covered countermeasures” by “covered persons” as those terms are defined by the PREP Act and the Secretary’s Declaration under the Act. Therefore, Plaintiffs’ Motion to Remand should be denied and Defendants should be permitted to file their Motion to Dismiss.

## II. LEGAL ARGUMENT

### A. OVERVIEW OF RECENT DECISIONS INVOLVING THE PREP ACT

Defendants previously filed a joint Statement of Supplemental Authority in Opposition to Motion to Remand (ECF Doc. No. 32), which addressed the competing decisions of *Garcia v. Welltower OpCo Group, LLC*, No. 8:20-cv-02250 (C.D. Cal. Feb. 10, 2021) and *Dupervil v. Alliance Health Ops. LLC*, No. 1:20-cv-04042, 2021 WL 355137 (E.D.N.Y. Feb. 2, 2021). The *Garcia* decision denied remand and granted dismissal under the PREP Act, whereas the *Dupervil* opinion granted remand of a case removed under the PREP Act.

Since that time, several other courts have considered the issue of removal jurisdiction under the PREP Act and, admittedly, most of them have found removal to be improper. *See, e.g. McCaleb v. AG Lynwood*, No. 2:20-cv-09746, 2021 WL 911951 (C.D.Cal. Mar. 1, 2021)

(**Exhibit A**); *Smith v. Colonial Care Ctr.*, No. 2:21-cv-00494, 2021 WL 1087284 (C.D.Cal. Mar. 19, 2021) (**Exhibit B**); *Lopez v. Life Care Ctrs. of America*, No. 1:20-cv-00958, 2021 WL 1121034 (D.N.M. Mar. 24, 2021) (**Exhibit C**); *Stone v. Long Beach Healthcare Ctr.*, LLC, No. 21-326 (C.D.Cal. Mar. 26, 2021) (**Exhibit D**); *Schuster v. Percheron Healthcare*, No. 4:21-cv-00156, 2021 WL 1222149 (N.D.Tx Apr. 1, 2021) (referring to a “growing consensus”) (**Exhibit E**); *Nava v. Parkwest Rehab. Ctr.*, No. 2:20-cv-07571, 2021 WL 1253577 (C.D.Cal. Apr. 5, 2021) (**Exhibit F**); *Bolton v. Gallatin Ctr. for Rehab. & Healing*, 3:20-cv-00683, 2021 WL 1561306 (M.D.Tn Apr. 21, 2021) (**Exhibit G**); *Shapnik v. The Hebrew Home for the Aged at Riverdale*, No. 20-cv-6774, 2021 WL 1614818 (S.D.N.Y. Apr. 26, 2021) (**Exhibit H**); *Thomas v. Century Villa*, No. 2:21-cv-03013 (C.D.Cal. Jun. 10, 2021) (**Exhibit I**); *Khalek v. South Denver Rehab.*, No. 1:20-cv-02240, 2021 WL 2433963 (D.Co Jun. 11, 2021) (**Exhibit J**); *Gwilt v. Harvard Square Retirement & Assisted Living*, No. 21-CV-0472, 2021 WL 2682614 (D.Co Jun. 30, 2021) (**Exhibit K**).

Nearly all of these decisions arise from cases brought against nursing homes or related entities for allegedly improper infection control. *But see Roebuck v. Mayo Clinic*, No. 21-cv-510, 2021 WL1851414 (D.A.Z. May 10, 2021) (medical malpractice claim involving an arterial blood gas stick test to assess blood oxygen levels for a COVID-19 diagnosis; following other district opinions to hold that the PREP Act does not trigger complete preemption; not addressing whether the claims fell under the PREP Act) (**Exhibit L**). The vast majority of these decisions rely primarily on the reasoning of *Dupervil* as persuasive and reject *Garcia* as an outlier.

In contrast, the court in *Rachel v. Natchitoches Nursing & Reab. Ctr.*, No. 1:21-cv-334 (W.D.L.A. Apr. 30, 2021) issued a Memorandum Ruling denying a motion to dismiss under the PREP Act, finding that it does trigger complete preemption doctrine. (**Exhibit M**). The *Rachal* matter involved a personal injury action asserting negligent infection control in a skilled nursing



facility leading to the death of a resident from COVID-19.<sup>2</sup> When considering its own subject-matter jurisdiction the *Rachal* court disagreed with the holding of *Dupervil. Id.*, n. 3. The *Rachal* court found the PREP Act to be particularly analogous to the Air Transportation Safety and System Stabilization Act (“ATSSSA”) because both statutes (1) create an administrative no-fault compensation fund; (2) provide broad immunity from suit for certain entities/individuals; (3) create an exclusive federal cause of action for certain residual claims; and (4) confer exclusive jurisdiction over such causes of action unto a specified federal venue. *Id.*, citing *In re WTC Disaster Site*, 414 F.3d 352 (2d Cir. 2005). Thus, the *Rachal* court concluded that:

Congress[] inten[ded] that the PREP Act exclusively encompass “claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” [42 U.S.C.] § 247d-6d(a)(1). Accordingly, to the extent Plaintiff’s alleged loss was caused by a “covered person” and arose out of, related to, or resulted from the administration to or the use by an individual of a “covered countermeasure,” this Court has federal question jurisdiction to apply the provisions of the PREP Act.

*Id.*

For the reasons that follow, Defendants submit that the decisions granting remand should not be followed. Although there can be no doubt that many more cases have granted remand than have denied it,<sup>3</sup> respectfully, all of the decisions granting remand rely on an erroneous application of precedent surrounding the issue of complete preemption and, in the process, threaten to upend

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<sup>2</sup> The *Rachal* matter was one of eight lawsuits filed against the same skilled nursing facility relating to residents’ contraction of COVID-19. The other seven lawsuits were remanded due to untimely removal, but the plaintiff in *Rachal* did not object to timeliness. The other seven lawsuits were as follows: (1) *Hayes v. Natchitoches Nursing & Reab. Ctr.*, No. 1:21-cv-00330 (W.D.La); (2) *Beaudion v. Natchitoches Nursing & Reab. Ctr.*, No. 1:21-cv-00329 (W.D.La); (3) *Gay v. Natchitoches Nursing & Reab. Ctr.*, No. 1:21-cv-00331 (W.D.La); (4) *Hamilton v. Natchitoches Nursing & Reab. Ctr.*, No. 1:21-cv-00333 (W.D.La); (5) *McClanahan v. Natchitoches Nursing & Reab. Ctr.*, No. 1:21-cv-00332 (W.D.La); (6) *Mills v. Natchitoches Nursing & Reab. Ctr.*, No. 1:21-cv-00336 (W.D.La); and (7) *Ratliff v. Natchitoches Nursing & Reab. Ctr.*, No. 1:21-cv-00335 (W.D.La). The court fully briefed on the impact of Advisory Opinion 21-01 and the issue of “complete preemption” in response to the motions to remand filed in these seven cases.

<sup>3</sup> Many of the remand decisions have been issued by the same judge in two or more different cases, and many substantively duplicative of other decisions even if not issued by the same judge. The cases cited herein in favor of remand are representative examples of the various lines of reasoning relied upon by district courts granting remand.

the critical role that the PREP Act plays within this nation’s public health emergency response framework.

**B. UNLIKE THE MANDATORY ARBITRATION PROVISIONS OF THE RAILWAY LABOR ACT, THE NO-FAULT BENEFITS UNDER THE PREP ACT DO NOT PRECLUDE THE APPLICATION OF THE COMPLETE PREEMPTION DOCTRINE**

Most of the courts granting remand have concluded that the PREP Act cannot trigger complete preemption because it provides an “administrative” remedy in the form of a no-fault benefits through the Covered Countermeasure Process Fund (“CCPF”) and the Countermeasures Injury Compensation Program (“CICP”), as opposed to an exclusive federal cause of action.<sup>4</sup> *See, e.g., McCaleb*, No. 2:20-cv-09746, 2021 WL 911951, \*\* 4-5 (C.D. Cal Mar. 1, 2021) (**Exhibit A**); *Smith*, No. 2:21-cv-00494, 2021 WL 1087284 (C.D.Ca Mar. 19, 2021) (**Exhibit B**); *Stone*, No. 21-326, \*\* 7-8 (C.D.Cal. Mar. 26, 2021) (**Exhibit D**); *Thomas*, No. 2:21-cv-03013 (C.D.Ca Jun. 10, 2021); *Gwilt*, No. 21-CV-0472, 2021 WL 2682614, \*4 (D.Co Jun. 30, 2021) (**Exhibit I**);

This line of reasoning appears to have its origin in the *Dupervil* decision, where the court cited *Sullivan v. Am. Airlines, Inc.*, 424 F.3d 267 (2d Cir. 2005) for the proposition that an administrative remedy is not a federal cause of action *per se*, and thus cannot be the basis for complete preemption because primary jurisdiction for such remedies lies with the agency. (Corresponding remand decisions from districts within the Ninth Circuit have relied on *Moore-Thomas v. Alaska Airlines, Inc.*, 553 F.3d 1241 (9th Cir. 2009) for the same position).

However, both *Sullivan* and *Moore-Thomas* are squarely distinguishable from cases implicating the PREP Act. There, the so-called “administrative remedy” at issue was a dispute resolution process, i.e., a mandatory arbitration requirement under the Railway Labor Act

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<sup>4</sup> The CCPF is the fund established by congress pursuant to 42 U.S.C. § 247d-6e. The CICP is the program administered by the Secretary of HHS to field applications for no-fault benefits paid by the fund. *See* 76 Fed. Reg. 62306 (final rule). Accordingly, the terms “CCPF” and “CICP” are often interchangeable.

(“RLA”). *See Sullivan*, 424 F.3d at 270 (2d Cir. 2005) (primary jurisdiction over “minor disputes” lies with arbitral panels); *Moore-Thomas*, 553 F.3d at 1245 (9th Cir. 2009) (“the RLA does not provide an exclusive federal cause of action... [it] instead requires submission of [minor] disputes to internal dispute-resolution processes and then to a division of the National Adjustment Board or an arbitration board selected by the parties.”). Thus, the Second and Ninth Circuits held that the RLA did not trigger complete preemption because the mandatory arbitration was not an “exclusive federal cause of action” between the parties in dispute. *See Sullivan*, 424 F.3d at 276 (2d Cir. 2005) (noting that the arbitral panels have primary jurisdiction over minor disputes under the RLA); *Moore-Thomas*, 553 F.3d at 1245 (9th Cir. 2009).

However, unlike the arbitration provisions of the RLA, the no-fault CICP/CCPF regime established by the PREP Act is *not* a dispute resolution process. Indeed, the defendant is not even a party to a claimant’s application for no-fault CICP/CCPF benefits. Therefore, unlike the arbitration panels under the RLA, the Secretary of HHS does not have primary jurisdiction over a potential dispute between the claimant and a “covered person”—the Secretary’s jurisdiction only extends to a determination as to no-fault benefit eligibility.

Moreover, under the PREP Act, the claimant has the sole ability to “elect” to proceed with a claim for “willful misconduct” if they chose—a choice over which a purported defendant has no control whatsoever. *See* § 247d-6e(d)(5) (election of remedies). This is not possible under the RLA. *See Andrews v. Louisville & N. R. Co.*, 406 U.S. 320, 322 (1972) (“the notion that the grievance and arbitration procedures provided for minor disputes in the Railway Labor Act are optional, to be availed of as the employee or the carrier chooses, was never good history and is no longer good law.”).

Another critical distinction between the RLA and the PREP Act for purposes of the complete preemption analysis is that the RLA does not create any federal cause of action at all, let alone an exclusive one, except to the extent of permitting judicial review of the arbitral decision. *See Andrews*, 406 U.S. at 325 (1972) (“A party who has litigated an issue before the Adjustment Board on the merits may not relitigate that issue in an independent judicial proceeding. He is limited to the judicial review of the Board's proceedings that the Act itself provides.”) (citations omitted). By contrast, the PREP Act plainly states that the only case in the entire country that can be brought against a “covered person” for a claim involving covered countermeasures is one for “willful misconduct” that must be brought in federal court, subject to specified procedures. *See* 42 U.S.C. § 247d-6d(c)-(e).

Further, the mere fact that a plaintiff who voluntarily chooses to bring a claim for “willful misconduct” must first apply for no-fault benefits does nothing to alter the complete preemption analysis because it does not change the fact that the statutorily-created claim for “willful misconduct” is the only judicially cognizable “cause of action” for claims related to the administration of covered countermeasures in any court in the United States. After all, if this line of reasoning were correct, then the Airway Transportation Safety and System Stabilization Act (“ATSSSA”) would not trigger complete preemption because, like the PREP Act, the ATSSSA establishes an administrative no-fault compensation regime as a trade-off for limited liability. *See In re WTC Disaster Site*, 414 F.3d 352, 373 (2d Cir. 2005) (“The principal components of the original enactment [of the ATSSSA] were the creation of the Victim Compensation Fund to provide relief, without litigation, to individuals (or relatives of deceased individuals) physically injured or killed as a result of the September 11 aircraft crashes; the limitation of the airlines’ liability for damages sustained as a result of those crashes; the creation of a federal cause of action

as the exclusive judicial remedy for damages arising out of those crashes; and the concentration in federal court in the Southern District of New York ... of suits on that federal cause of action”) (citations omitted).<sup>5</sup>

In fact, the PREP Act even tolls the running of the statute of limitations for a “willful misconduct” claim while the no-fault application benefit is pending. *Compare* § 247d-6e(d)(2) (tolling of statute of limitations while no-fault application is pending) *with* § 247d-6d(e)(4)(A) (non-compliant complaint for “willful misconduct” does not stop the statute of limitations from running). This confirms that, unlike the arbitration panels at issue in the RLA, the Secretary of HHS does not have primary jurisdiction over a dispute between a claimant and a “covered person.”

Thus, the concerns at play in *Sullivan* and *Moore-Thomas* are not applicable to the PREP Act, and those decisions do not support the holding that the PREP Act does not have a completely preemptive impact on claims within its ambit. The mere fact that the RLA and the PREP Act both provide remedies that are “administrative” in nature does not mean that those remedies are the same for the purpose of a complete preemption analysis. Rather, the critical distinction between the RLA and the PREP Act is also the very essence of the complete preemption analysis: the creation of an exclusive federal cause of action to adjudicate the dispute between the parties.

Accordingly, those cases that rely on the reasoning of *Sullivan* and *Moore-Thomas* to support the conclusion that the PREP Act’s administrative remedies through the CICP/CCPF preclude application of the complete preemption doctrine should not be followed. The PREP Act is an unusual statute reserved for drastic times; although it is not identical to the ATSSSA or any

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<sup>5</sup> The courts to have considered this issue typically hold that the PREP Act does not warrant the same treatment as the ATSSSA because the ATSSSA contains a provision creating a federal cause of action for all claims “related to” the 9/11 attacks, whereas the PREP Act only provides a narrow cause of action for “willful misconduct.” This point is addressed below, and, in any event, it does nothing to explain why the mere provision of no-fault benefits would prevent application of the complete preemption doctrine to statute that otherwise meets the criteria.

other statute triggering complete preemption, it nevertheless shares the same key characteristics. Like those other statutes, the PREP Act triggers complete preemption, and Plaintiffs’ Motion to Remand should be denied because the claim provides notice of a set of facts for which there can only be one cause of action asserted—a federal cause of action for willful misconduct under the PREP Act.

**C. WHETHER A PLAINTIFF HAS AN ACTIONABLE CLAIM FOR “WILLFUL MISCONDUCT” UNDER THE PREP ACT IS IRRELEVANT TO THE COMPLETE PREEMPTION ANALYSIS**

Many courts granting remand have reasoned that the PREP Act does not trigger complete preemption for negligence claims because it does not provide a federal equivalent to a state negligence claim. *See, e.g., Lopez*, No. 1:20-cv-00958, 2021 WL 1121034, \*\* 9-15 (D.N.M. Mar. 24, 2021) (**Exhibit C**) (finding that the a claim is not completely preempted under the PREP Act unless it falls within either the willful misconduct exception or the CICP/CCPF no-fault regime); *Smith*, No. 2:21-cv-00494, 2021 WL 1087284 (C.D.Ca Mar. 19, 2021) (**Exhibit B**); *Schuster v. Percheron Healthcare*, No. 4:21-cv-00156, 2021 WL 1222149, \* 4 (N.D.Tx Apr. 1, 2021) (**Exhibit E**) (finding that the ATSSSA created a cause of action for all claims “related to” the 9/11 attacks, whereas the PREP Act only created a narrow exception); *Bolton*, 3:20-cv-00683, 2021 WL 1561306, \*\* 6-8 (M.D.Tn Apr. 21, 2021) (**Exhibit G**); *Khalek*, No. 1:20-cv-02240, 2021 WL 2433963, \*\* 4-6 (D.Co Jun. 11, 2021) (**Exhibit J**).

These courts typically reason that the “willful misconduct” exception is very narrow, and thus not a true “substitute” cause of action to a claim for negligence. Put differently, these courts reason that claims at issue were not completely preempted because the “willful misconduct” exception did not encompass all causes of action contained within the four corners of the pleadings. In essence, therefore, these courts effectively make the doctrine of complete preemption conditional on whether the plaintiff would be entitled to relief through the exclusive federal cause

of action provided, instead of on whether congress has mandated that the federal cause of action provided be the exclusive cause of action available.

However, this reasoning turns the complete preemption analysis on its head. As the Supreme Court’s analysis in *Beneficial* makes clear, the focus of the complete preemption doctrine is not whether there is an entitlement to relief under the federal cause of action provided, but whether the federal cause of action provided is, or would be, the “exclusive” cause of action available for the class of claims preempted. *See Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 8 (2003); *Anderson v. Elec. Data Sys. Corp.*, 11 F.3d 1311, 1314 (5th Cir 1994); *Cannon v. Group Health Serv. of Oklahoma, Inc.*, 77 F.3d 1270, 1274 (10th Cir 1996).

Indeed, for purposes of the complete preemption analysis, it is irrelevant whether the exclusive federal remedy provided by statute is broader or narrower in scope than the state cause of action being preempted. *See Caterpillar, Inc. v. Williams*, 482 U.S. 386, 391, n. 4 (1987) (rejecting the court of appeals’ reasoning that “that a case may not be removed to federal court on the ground that it is completely pre-empted unless the federal cause of action relied upon provides the plaintiff with a remedy”); *Aetna Health Inc. v. Davila*, 542 U.S. 200, 208-09 (2004) (discussing ERISA as a “comprehensive civil enforcement scheme that represents a careful balancing” of competing interests by congress, such that state law may not provide broader civil enforcement remedies); *Avco Corp. v. Aero Lodge No. 735, Int’l Ass’n of Machinists & Aerospace Workers*, 390 U.S. 557, 561 (1968) (“the breadth or narrowness of the relief which may be granted under federal law... is a distinct question from whether the court has jurisdiction over the parties and the subject matter.”); *Fayard v. Ne. Vehicle Servs., LLC*, 533 F.3d 42, 46 (1st Cir. 2008) (“For complete preemption to operate, the federal claim need not be co-extensive with the ousted state claim. On

the contrary, the superseding federal scheme may be more limited or different in its scope and still completely preempt.”).

It is therefore possible that a claimant can be left without a remedy after the application of the complete preemption doctrine. *See La Buhn v. Bulkmatric Transp. Co.*, 644 F. Supp. 942, 948 (N.D. Ill 1986) (“As is typical in these preemption cases, a removing defendant tows the case into the federal harbor only to try to sink it once it is in port.”) *aff’d* 865 F.2d 119 (7th Cir. 1988). After all, if that were not the law, then every time a defendant asserted complete preemption they would effectively be simultaneously conceding that the plaintiff has a claim against them in the first place pursuant to that exclusive federal cause of action. However, a removing defendant does not waive the right to bring a Rule 12(b)(6) motion for failure to state a claim merely by removing the case in the first place under the doctrine of complete preemption. *See id.*

Here, the right asserted in the Complaint is the right to seek recovery from Defendants for the injuries alleged. The PREP Act does create a cause of action to vindicate that right—it just limits recovery to instances of “willful misconduct” instead of mere negligence, and requires a plaintiff to follow specified procedures when bringing such a claim. Substantively, this merely replaces the common law analysis of “duty” and “breach” with a statutorily proscribed theory. And procedurally, this framework confirms a congressional intent to exercise federal jurisdiction over the subject matter. Indeed, the claim for “willful misconduct” would seek recovery for the same injuries as alleged in a preempted negligence claim. Thus, unlike the instances where no complete preemption is found, the PREP Act does not provide no federal cause of action whatsoever to vindicate the rights at issue—it just does not guarantee that every plaintiff will be entitled to the same recovery that might be available under common law within a state tort system.



Therefore, the reasoning adopted by the vast majority of district courts granting remand of cases removed under the PREP Act—that complete preemption cannot apply if the claimant would not be entitled to recover under a theory of “willful misconduct”—is erroneous and should not be followed. It is irrelevant for the purposes of complete preemption whether the exclusive cause of action created by statute is broader or narrower than the state cause of action that is preempted. What does matter is that the statute creates an exclusive federal cause of action for all preempted claims in the first place. Because the PREP Act does just that, complete preemption applies, notwithstanding the fact that a claim for “willful misconduct” is narrower than a claim for negligence.

**D. WHETHER A PLAINTIFF AFFIRMATIVELY ALLEGES “WILLFUL MISCONDUCT” IS IRRELEVANT TO WHETHER THE CLAIM FALLS UNDER THE PREP ACT FOR THE PURPOSE OF COMPLETE PREEMPTION**

Some courts have reasoned that a claim does not trigger complete preemption under the PREP Act if the plaintiff does not affirmatively allege a claim for willful misconduct within the complaint. *See, e.g., Shapnik*, No. 20-cv-6774, 2021 WL 1614818, \* 11 (S.D.N.Y. Apr. 26, 2021) (**Exhibit H**).

However, this reasoning overlooks the fact that “complete preemption” is, by definition, only applicable when a claimant does not plead the case under federal law to begin with. Otherwise, there would be no need to undertake the “artful pleading” analysis that underlies the application of the “complete preemption” doctrine.

Here, Plaintiffs’ Complaint is removable under the “complete preemption” doctrine notwithstanding the fact that they do not expressly assert the “willful misconduct” exception under the PREP Act.

**E. ADVISORY OPINION 21-01 IS “PERSUASIVE” WITH RESPECT TO THE ISSUE OF COMPLETE PREEMPTION**

The *Rachal* court acknowledged that deference should be afforded to Advisory Opinion 21-01. *Rachal*, No. 1:21-cv-334, \* 11 (W.D.L.A. Apr. 30, 2021) (**Exhibit M**). It reasoned that (1) the PREP Act gave broad authority to HHS; (2) HHS had incorporated its own advisory opinions into the PREP Act Declarations; (3) the PREP Act presented a complex statutory framework; (4) the PREP Act applied to technical subject matter; and (5) there was a need for uniformity in the interpretation of the PREP Act across the united states. *Id.*, citing *Chevron, Inc. v. NDRC, Inc.*, 467 U.S. 837, 843 (1984); *United States v. Mead Corp.*, 533 U.S. 218, 220 (2001). The court further reasoned that even if *Chevron* deference were not applicable, HHS’s interpretation of the PREP Act as expressed in its advisory opinions and various declarations was “reasonable.” *Id.*, citing *Kornman & Associates, Inc. v. United States*, 527 F.3d 443, 455 (5th Cir. 2008).

By contrast, virtually all of the remand decisions cited above reject Advisory Opinion 21-01 as “not persuasive” to the extent that it applies the complete preemption doctrine. However, for the reasons above, these courts’ underlying treatment of the complete preemption doctrine is erroneous to begin with.

Moreover, these district courts do not account for the fact that the treatment of the issue of complete preemption within Advisory Opinion 21-01 is premised on an underlying analysis of the framework of the PREP Act as applied to the COVID-19 pandemic—something well within the technical expertise of HHS. *See* Advisory Opinion 21-01 at pp. 2-4 (explaining that the broad preemptive scope of the PREP Act, as evidenced by the phrase “related to,” applies to claims of inaction so long as they do not allege complete inaction, and encouraging courts to permit jurisdictional discovery when it is unclear whether such complete inaction is alleged).

Therefore, those decisions rejecting Advisory Opinion 21-01 should not be followed. Advisory Opinion 21-01 reflects an informed understanding of the PREP Act and its complex statutory framework as applied to the COVID-19 pandemic. It should be afforded deference.

**F. IT IS IMPROPER TO REJECT THE SECRETARY’S FORTH AMENDMENT TO THE DECLARATION SOLELY BECAUSE THE COURT DOES NOT AGREE WITH ITS APPLICATION OF *GRABLE***

Many courts have rejected the Fourth Amendment to the Declaration, which expressly states that claims implicating the PREP Act present “substantial federal questions” within the meaning of *Grable & Sons Metal Prods. v. Darue Eng’g & Mfg.*, 545 U.S. 308 (2005)—which held that cases presenting “substantial federal questions” are removable. *See, e.g., McCaleb*, No. 2:20-cv-09746, 2021 WL 911951, \* 3 (C.D. Cal Mar. 1, 2021) (**Exhibit A**); *Stone*, No. 21-326, \*\* 9-10 (C.D. Cal. Mar. 26, 2021) (**Exhibit D**); *Bolton*, 3:20-cv-00683, 2021 WL 1561306 \* 5 (M.D. Tn Apr. 21, 2021) (**Exhibit G**).

These courts acknowledge, implicitly or explicitly, the Secretary’s manifest intent behind the citation to *Grable*: that claims implicating the PREP Act should be removable. However, they reject removal jurisdiction because they disagree with the Secretary’s application of the *Grable* rule. As such they essentially render the *Grable* citation and the Secretary’s statement a nullity.

The application of the *Grable* doctrine was addressed at length in prior briefing and will not be repeated here. However, it is notable that some courts have erroneously treated that amended declaration as an advisory opinion, even though it was a final agency action. Moreover, although some courts have implicitly or explicitly concluded that that the Secretary’s attempt to apply the *Grable* doctrine was beyond the bounds of his authority under the PREP Act, all of these courts overlook the significant public health benefit to a uniform application of the PREP Act across the 50 states.

Under the express language of the PREP Act, it is the Secretary who is given the authority to administer the statute. *See* 42 U.S.C. § 247d-6d(b)(1) (“the Secretary may make a declaration ... recommending, *under conditions as the Secretary may specify*, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended”) (emphasis supplied). Therefore, if the Secretary wishes to recognize removal jurisdiction for claims implicating the PREP Act during a public health emergency, particularly on the theory that it would benefit the nationwide response to the pandemic, then he was free to do so, and that decision is not reviewable by any court. § 247d-6d(b)(7). Indeed, such authority is at least implicitly conferred under 42 U.S.C. § 247d(a)(2), which provides that the Secretary “may take such action as may be appropriate to respond to the public health emergency” once it is declared).

The lack of deference to the secretary towards the manner in which he carried out his congressionally mandated task of leading the nation’s response to the COVID-19 pandemic is more problematic than whether the reasoning offered by the secretary to accomplish his goal comports with the courts’ view of precedent established in other procedural contexts. This is not a situation where an agency sought to preemptively limit the court’s ability to review its own determination of a dispute. Rather, the Secretary sought to expand judicial review, and did so with the combined authority of the legislature and the executive branch during a declared public health emergency. Moreover, neither branch has since rejected the Secretary’s determination that removal jurisdiction applies under the PREP Act, and the current Secretary has kept the declaration and all of its amendments in full force.

Therefore, even if this court ultimately agrees with the other district courts that the *Grable* doctrine would not, on its own, apply to claims removed under the PREP Act, it should

nevertheless strive to give effect to the Secretary’s unequivocal pronouncement, made by final agency action, that claims implicating the PREP Act are removable to federal court. To disregard such intent would ignore the unique technical expertise of the secretary in responding to the COVID-19 pandemic, and would further disregard the balance of power envisioned by Congress during a national public health emergency.

**G. THE PREP ACT WOULD NOT PROVIDE ANY IMMUNITY “FROM SUIT” IF ITS APPLICATION HINGED ON WHETHER THE PLAINTIFF AFFIRMATIVELY PLEADED THAT A FAILURE TO USE A COUNTERMEASURE WAS DUE TO THE DEFENDANTS’ ALLOCATION OF SCARCE RESOURCES**

The original briefing to the present Motion to Remand addresses at length why Plaintiffs’ allegations fall under the preemptive scope of the PREP Act—namely, that they necessarily “relate to” and “arise out of” Defendants’ use and administration of various covered countermeasures, including respirators, oxygen delivery systems, anticoagulant drugs, and various medical devices for the purpose of treating Plaintiffs’ ward for COVID-19 pneumonia. Without re-addressing the underlying arguments, it presently suffices to note that Plaintiffs’ central counterargument was that the complaint, really, was about inaction as opposed to action.

In Advisory Opinion 21-01 the OGC to the Secretary of HHS rejected the “use versus non-use” distinction under the PREP Act, and explained that only an allegation of complete inaction will bring a claim of negligent infection control outside of the PREP Act. Advisory Opinion 21-01, pp. 2-4. Notwithstanding, many district courts have continued to adopt the false dichotomy of “action versus inaction” within their analysis of the PREP Act’s scope. *See, e.g., McCaleb*, No. 2:20-cv-09746, 2021 WL 911951, \*\* 5-6 (C.D. Cal Mar. 1, 2021) (**Exhibit A**); *Smith*, No. 2:21-cv-00494, 2021 WL 1087284 (C.D.Ca Mar. 19, 2021) (**Exhibit B**); *Lopez*, No. 1:20-cv-00958, 2021 WL 1121034, \*\* 9-14 (D.N.M. Mar. 24, 2021) (**Exhibit C**); *Stone*, No. 21-326, \*\* 6-7 (C.D.Cal. Mar. 26, 2021) (**Exhibit D**).

Moreover, many of these opinions have held that the PREP Act would only apply to non-use or non-administration if the plaintiff affirmatively alleged that the non-use or non-administration was the product of some resource allocation decision. *See, e.g., Nava*, No. 2:20-cv-07571, 2021 WL 1253577, \*\* 2-3 (C.D.Cal Apr. 5, 2021) (**Exhibit F**).

In effect, these decisions would therefore permit a plaintiff to completely side-step PREP Act immunity by merely omitting any reference to covered countermeasures, or the allocation thereof, in a pleading.

It is not hyperbole to state that this line of reasoning threatens the core functionality of the PREP Act, which aims to provide immunity “from suit.” Under a notice pleading standard, which governs most state law claims, there is no obligation to state in the pleadings the precise departure alleged in a medical malpractice case, let alone whether that departure was related to a defendants’ allocation of scarce resources. It is safe to assume that congress was aware of this when they drafted the PREP Act and did not intend to draft a statute that could be so easily circumvented. Thus, to require a plaintiff to plead with such detail before even considering the application of the PREP Act is to effectively erase the phrase “immune from suit” from the statute. This Court should not adopt such a construction of the PREP Act.

Here, for the reasons set forth in the initial briefings, this claim clearly relates to and arises out of Defendants’ affirmative administration and use of covered countermeasures. Moreover, to the extent that Plaintiffs point to momentary omissions, those are covered under the PREP Act as well. Therefore, the claim falls under the PREP Act, Plaintiffs’ motion to remand should be denied, and Defendants’ should be permitted to file their motion to dismiss.

### **III. CONCLUSION**

Defendants submit that the *Rachal* opinion correctly applied the doctrine of “complete preemption” and also afforded an appropriate degree of deference to HHS’s broad interpretation

of the preemptive impact of the PREP Act and the immunity it confers. Respectfully, the *Dupervil* court and its various progeny should not be followed as those courts erroneously analogize the PREP Act to the RLA as opposed to the ATSSSA, with which it shares many key characteristics, and improperly condition the complete preemption analysis on whether the plaintiff would be entitled to relief under a theory of “willful misconduct.” The PREP Act triggers “complete preemption” because it broadly preempts all claims “relating to” the administration of covered countermeasures while simultaneously providing that the exclusive remedy *between the parties* shall be a new federal cause of action for “willful misconduct” brought in the District Court for the District of Columbia. Accordingly, Plaintiff’s Motion to Remand should be denied because the claim plainly “relates to” the administration of covered countermeasures.

Dated: New York, New York  
July 13, 2021

Yours, etc.,

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